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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/022,809	02/08/2011	Robert F. Hurt	M190.249.103	7432

63496 7590 01/31/2017

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EXAMINER

KLEIN, BENJAMIN JACOB

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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01/31/2017

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROBERT F. HURT

Appeal 2015-004011
Application 13/022,809
Technology Center 3700

Before JENNIFER D. BAHR, LINDA E. HORNER, and
BRANDON J. WARNER, *Administrative Patent Judges*.

WARNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Robert F. Hurt (“Appellant”)¹ appeals under 35 U.S.C. § 134(a) from the Examiner’s decision rejecting claims 1 and 6–18, which are all the pending claims. Appeal Br. 1, 3. We have jurisdiction over the appeal under 35 U.S.C. § 6(b).

We REVERSE.

¹ According to Appellant, the real party in interest is Medtronic PS Medical, Inc. Appeal Br. 3.

CLAIMED SUBJECT MATTER

Appellant's disclosed invention "relates to a method of draining cerebrospinal fluid." Spec. ¶ 2. Claim 1, reproduced below, is the sole independent claim and is representative of the subject matter on appeal.

1. A method of draining cerebrospinal fluid from a human brain, the method comprising:

providing a drainage catheter having a proximal end and a distal end, wherein the drainage catheter has a plurality of openings formed therein, wherein the plurality of openings includes a first opening, a second opening, and a most proximal opening, wherein the second opening is disposed closer to the distal end than the first opening and wherein a cross-sectional area of the first opening is less than a cross-sectional area of the second opening;

inserting the distal end of the drainage catheter into a human brain;

diverting excess cerebrospinal fluid from the human brain, wherein the cerebrospinal fluid passes into the drainage catheter through the plurality of openings and out of the drainage catheter through the proximal end; and

distributing the draining of the cerebrospinal fluid between the plurality of openings, wherein the distributed flow of cerebrospinal fluid delays or prevents occlusion of the catheter caused by choroid plexus tissue being drawn into the plurality of openings.

EVIDENCE

The Examiner relied on the following evidence in rejecting the claims on appeal:

Kirsch	US 5,385,541	Jan. 31, 1995
Deniega	US 2002/0082547 A1	June 27, 2002

REJECTION

The following rejection is before us for review: Claims 1 and 6–18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kirsch and Deniega. Final Act. 4–11.

ANALYSIS

Independent claim 1 recites, in relevant part, a method of draining cerebrospinal fluid (“CSF”) comprising the step of providing a drainage catheter having “a first opening, a second opening, and a most proximal opening, wherein the second opening is disposed closer to the distal end than the first opening and wherein a cross-sectional area of the first opening is less than a cross-sectional area of the second opening.” Appeal Br. 10, Claims App. Appellant argues that the claimed subject matter would not have been obvious because there is no reason to modify the method of Kirsch based on the teachings of Deniega to use a catheter having the claimed opening configuration. *See id.* at 6–8. In particular, Appellant asserts that one of ordinary skill in the art would not have been led “to use the [infusion] catheter hole configuration disclosed in Deniega in conjunction with the CSF drainage system disclosed in Kirsch to reduce the blockage of the holes in the CSF drainage catheter.” *Id.* at 8; *see* Reply Br. 2. We agree that a sustainable case of obviousness has not been established.

In rejecting independent claim 1, the Examiner found that Kirsch discloses a method of draining cerebrospinal fluid, substantially as claimed, including providing a drainage catheter with a plurality of openings, inserting the catheter into a human brain, and draining excess fluid through

the plurality of openings. *See* Final Act. 4. The Examiner acknowledged that Kirsch does not disclose “that a cross-sectional area of the first opening is less than a cross-sectional area of the second opening, or that the distributed flow of cerebrospinal fluid avoids choroid plexus tissue from being drawn into the plurality of openings.” *Id.* at 5. However, the Examiner found that Deniega discloses “a catheter for CSF applications wherein a cross-sectional area of the first opening is less than a cross-sectional area of the second opening (Fig. 8) and teaches that this configuration of holes provides a uniform flow for the infusion of fluids such as medications through the catheter.” *Id.* The Examiner concluded that, given the teachings of the prior art, “it would have been obvious to a person having ordinary skill in the art at the time of the invention to replace the hole configuration of Kirsch with the hole configuration of Deniega in order to allow for uniform delivery through the holes.” *Id.* According to the Examiner, “one of ordinary skill would recognize that the hole configuration of Deniega would create a uniform flow for the draining of fluids as well as their delivery.” *Id.*

Here, the Examiner erred by not articulating sufficient reasoning supported by rational underpinnings why a person having ordinary skill in the art would have been prompted to modify the drainage catheter used in the method of Kirsch to include the opening configuration of Deniega’s infusion catheter. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (stating that “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006))).

Kirsch discloses that “ventricle tube **22** of the shunt **20** comprises a series of holes **21**” for draining cerebrospinal fluid. Kirsch, col. 5, ll. 14–16. Kirsch also discloses “an external conduit **54** for providing therapeutic medications to the tissue surrounding the shunt **20**.” *Id.* at col. 6, ll. 1–3. Kirsch explains that “antibiotic will travel down the conduit **54**, exiting into the tissue surrounding the shunt **20** through the drain holes **56**.” *Id.* at col. 9, ll. 43–45. In this regard, Appellant correctly notes that “the Kirsch catheter [(i.e., CSF drainage tube 22)] is not used for infusion of antibiotics,” but, “[r]ather, Kirsch indicates that an external conduit system [(i.e., infusion conduit 54)] is used for delivering the antibiotics.” Reply Br. 2.

Deniega discloses that “[c]atheter **60** is . . . suited for relatively high flow rate delivery of fluid to a region with an anatomical system.” Deniega ¶ 49. Deniega explains that, “for high or low pressure fluid delivery, exit holes nearer to the distal end of a catheter tube generally have increased flow resistance compared to exit holes nearer to the proximal end of the tube,” and “the fluid flowing through the more distal holes experiences a greater pressure drop.” *Id.* ¶ 50. Deniega discloses that “[c]atheter **60** includes a tube **62** having a plurality of exit holes **64** of increasing size,” such that “the more distal exit holes are larger in diameter than the more proximal exit holes.” *Id.* ¶ 49. According to Deniega, “the larger size of the more distal holes compensates for their increased flow resistance and pressure drop.” *Id.* ¶ 50; *see also id.* (disclosing that “catheter **60** advantageously provides substantially uniform fluid *delivery* through substantially all of the exit holes **64**, under relatively high flow rate conditions” (emphasis added)).

We agree with Appellant that the Examiner has not provided adequate factual evidence or persuasive technical reasoning to explain how or why

“the differently size openings [of Deniega] would be beneficial at dispersing the flow of cerebrospinal fluid *into the drainage catheter*” of Kirsch. Reply Br. 2 (emphasis added). In particular, the Examiner does not offer any evidence or reasoning to support the position that “one of ordinary skill would recognize that the hole configuration of Deniega would create a uniform flow for the draining of fluids as well as their delivery.” Final Act. 5.

Rejections based on obviousness must rest on a factual basis; in making such a rejection, the Examiner has the initial burden of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions, or hindsight reconstruction to supply deficiencies in the factual basis. *See In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967). Absent improper hindsight reconstruction, we fail to see a sufficient reasoned explanation based on a rational underpinning as to why one of ordinary skill in the art would have been led to modify the drainage tube used in Kirsch’s cerebrospinal fluid drainage method to include Deniega’s fluid delivery opening configuration, and a reason for such modification is not otherwise evident from the record.

Accordingly, based on the record before us, the Examiner has not met the burden of establishing a prima facie case of obviousness. On this basis, we do not sustain the rejection of independent claim 1, and of dependent claims 6–18, as being unpatentable over Kirsch and Deniega.

Appeal 2015-004011
Application 13/022,809

DECISION

We REVERSE the Examiner's decision rejecting claims 1 and 6–18 under 35 U.S.C. § 103(a) as being unpatentable over Kirsch and Deniega.

REVERSED